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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,212	07/15/2003	Thomas L. Merrill		8748

7590 08/11/2005

Thomas L. Merrill
25 Lynnfield Dr.
E. Windsor, NJ 08520

EXAMINER

MENDEZ, MANUEL A

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/620,212

Applicant(s)

MERRILL ET AL.

Examiner

Manuel Mendez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05/26/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 14-43 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. **Claims 14-31**, drawn to a multi-lumen catheter including a working fluid transfer pathway; a first manifold for connecting the multi-lumen catheter to a return pathway; a heterogeneous and compliant heat exchange portion connected to said first manifold, the heat exchange portion having a plurality of dynamic surface regions that provide internal and external boundary layer disruption; a second manifold connected to the heat exchange portion that distributes the working fluid through the heat exchange portion; and a high frequency working fluid pressure oscillator adapted to create surface dynamics in the heat exchange portion, classified in class 604, subclass 113.
- II. **Claims 32-37**, drawn to a single lumen catheter including a working fluid pathway; a compliant connective element connecting the single lumen catheter to a first manifold, the first manifold connecting said compliant connective element to a compliant heat exchange surface; wherein during operation of the heat transfer device, the compliant heat exchange surface moves normal to and tangential to the longitudinal axis of the heat transfer device; and a second manifold connected to said compliant heat exchange surface adapted to collect working fluid that exits the compliant heat exchange surface; and a delivery device adapted to deliver working

fluid to the inflatable distal manifold and remove working fluid from the inflatable distal manifold, thereby creating heat exchange surface dynamics, classified in class 604, subclass 114.

- III. Claims 38-42, drawn to a multi-lumen catheter for providing a working fluid pathway; a proximal manifold for connecting said multi-lumen catheter, distributing the working fluid, and driving rotary motion of a compliant heat exchange surface, a compliant heat transfer device, exchange surface that spins about the longitudinal axis of the heat a distal manifold connected to said heat exchange surface adapted to collect the working fluid inside the said heat exchange surface; and a control system adapted to circulate the working fluid and drive the rotary motion of the proximal manifold; whereby the heat exchange process is augmented by creating a circumferential heat exchange surface motion, classified in class 604, subclass 291.
- IV. Claim 43, drawn to a method for altering an organ temperature, classified in class 604, subclass 500.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the method can

be used with a materially different apparatus since the method requires the use of apparatuses that are not positively disclosed in the apparatus claims.

Inventions I, II and III are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, inventions I, II, III have separate utility in view of the structural differences as indicated in the Groups above. See MPEP § 806.05(d).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

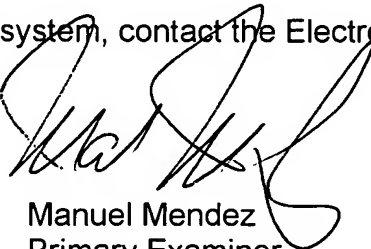
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel Mendez whose telephone number is 703-272-4977. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Manuel Mendez', is written over the text of the Electronic Business Center (EBC) contact information.

Manuel Mendez
Primary Examiner
Art Unit 3763

MM